JS 10/1/21
RJA 01/04/22

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. EPA concludes there is low-moderate concern for human health hazard for the chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard (toxicity test data on analogue).

Based on the hazard determination and available qualitative risk information, EPA concludes that there are risks for the PMN substance.

SUMMARY INFORMATION

Human Health Hazard:

- Lower molecular weight components of the PMN substance are expected to be poorly absorbed via all routes of exposure.
- Concern for lung toxicity (hydrocarbon pneumonia) from aerosol inhalation.
- Concern for dermal irritation based on submitted test data for branched and linear alkanes.

Human Health Risk:

- Irritation following dermal exposure to workers was not quantified due to a lack of dose-response for this hazard. Irritation hazards may be mitigated by use of appropriate PPE, including impervious gloves.
- Risks to workers from aerosol inhalation were calculated, but deemed unlikely under the conditions of use based on the physical/chemical properties of the PMN substance which are expected to limit aerosol formation (vapor pressure) and increase lung clearance (low molecular weight, carbon number and viscosity).
    - Risks were not identified for workers via inhalation based on quantitative hazard data for the analogue, C20-C50 hydro-treated oil (MOE = 160; benchmark MOE = 100).
    - Risks were not identified for the general population via inhalation based on quantitative hazard data for analogue, C20-C50 hydro-treated oil (MOE=7E+3; benchmark MOE= 100).
    - Risks were not identified for consumers via inhalation based on quantitative hazard data for the analogue, C20-C50 hydro-treated oil (MOE =7E+3; benchmark MOE = 100).
- Irritation to consumers following dermal exposure was not quantified due to a lack of dose-response for this hazard.
- Risks to workers from vapor inhalation are not expected based on quantitative analogue data [redacted] indicating no observed treatment effects up to the highest concentration tested (NOEC = 10,400 mg/m^3).

Potentially Useful Information:

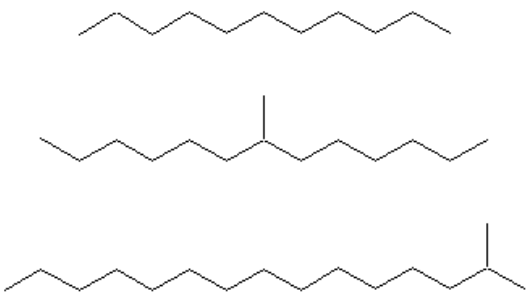
Potentially useful information would inform understanding of irritation and pulmonary effects.

PART A

SAT Date: 07/19/16

Health Assessor: S. Oxendine

Structure:



- **CASRN:** 173091-79-7
- **PMN Health Rating:** 1-2
- **SAT Key Words:** LUNG; AQUATOX
- **Absorption:** Lower molecular weight components of the PMN substance are expected to be poorly absorbed via all routes of exposure.
- **SAT Health Summary:** There is concern for lung toxicity (hydrocarbon pneumonia) if inhaled. Concern for dermal irritation based on submitted data for C11-C16 Alkanes
- **PMN Data:** (study summary, POD)
    - None submitted
- **Analogue Data:**
    - Toxicity Data for Alkanes branched and linear from read across submission (Studies cited but not submitted)
    - Acute Toxicity: Low by analogy to similar GTL Solvent fractions (GTL, USA, 2016)
        - > 5,000 mg/kg Oral LD50
        - > 2,000 mg/kg Dermal LD50
        - > 9300 mg/m^3 (saturated vapor)

    (Note: the PMN substance may present an aspiration hazard when tested in aerosol form)

    - Irritation: Not irritating to skin or eyes by analogy to similar GTL Solvents (GTL USA, 2016)
    - Sensitization: Not sensitizing by analogy to similar GTL Solvents (GTL USA 2016)
    - Reproductive Effects: Low by analogy to similar GTL Solvents, NOAEL > 750 mg/kg-day (highest dose tested) (GTL USA 2016)

- Developmental Effects: Low by analogy to similar GTL Solvents, NOAEL > 866 mg/kg-day (highest dose tested) (GTL USA 2016)
- Mutagenicity: Low by analogy to similar GTL Solvents. (All tested GTL Solvents within the C8-C24 range are not mutagenic in the *Salmonella typhimurium* and in the *Escherichia coli* reverse mutation assays.

- **Point of Departure Selected and Basis:**
  - From C14-C20 OECD SIDS Document:
    - no effects up to 3,000 mg/kg oral repro/developmental
    - no systemic effects up to 5,000 mg/kg oral
    - no effects reported for vapor exposure up to 10,400 mg/m^3
    - NOEC = 1000 mg/m^3 for read across from C10-C12 (aerosol exposure)

Note: No repeated-dose inhalation toxicity studies were located for the C14-C20 Aliphatic Hydrocarbon solvents category. Using a read-across approach, a repeated-dose inhalation study for a C9-C14 Aliphatic Hydrocarbon solvents category substance was used to inform hazards associated with the PMN. More specifically, [redacted] (< 2% aromatics; [redacted]) administered to rats via inhalation at 0, 2600, 5200 or 10,400 mg/m^3 vapor for 6 hours/day, 5 days/week for 13 weeks (similar to OECD 413) showed no adverse effects at any concentration tested. Based on this observation, the no observed effect concentration (NOEC) = 10,400 mg/m^3 was selected as the point of departure for risk estimation.

Data on a C20-C50 hydro-treated oil ([redacted] average carbon number = C35) also showed minimal inhalation toxicity in rats at aerosol levels up to the highest concentration tested (1000 mg/m^3) for 28 consecutive days (similar to OECD 412). The only treatment-related effect observed in this study was increased lung weight. Study authors noted this effect is likely related to the accumulation of oil-laden lung macrophage. This finding is consistent with other published studies showing a progressive accumulation of alveolar macrophage as a result of increased lung deposition of aerosolized oil particles. A NOEC = 220 mg/m^3 (analytical) was identified for C20-C50 hydro-treated oil based on the accumulation of lung macrophage. This effect level was not selected as a point of departure for the current assessment because the physical/chemical properties of the PMN substance (e.g., higher vapor pressure, lower molecular weight and carbon number) are expected to limit the potential for accumulation of aerosolized oil particles and increase clearance in the lung, resulting in a decreased hazard concern relative to C20-C50 hydro-treated oil. As such, the highest concentration tested (NOEC = 1000 mg/m^3) was selected as the POD for risk estimation.

Exposure Routes of Interest:

- _X_Inhalation: [Rationale if excluded]
- _X_Dermal: [Rationale if excluded]
- __Ingestion: [Rationale if excluded] (PMN does not present a hazard concern via this route.)

PART B

Focus Date: 09/08/2016

Focus Assessor: S. Oxendine

- **Uses:** Solvent/diluent in coatings (25%), cleaning fluids (9.5%), agrochemicals (3.2%), and metalworking fluids/rolling oils (8.9%), and as a chemical intermediate (53.4%). [redacted]

- **Worker Exposure:**

  PROC: Transport from import tankers to domestic transport containers
  - **Inhalation (Vapor)**: PDR = 5.6E+3 mg/day over 250 days/yr
  - **Dermal (Liquid 100.00% concentration):** 2.2E+3 mg/day over 250 days/yr (Loading Liquid Product into Tank Trucks)

  PROC1: Formulation of Coatings, Inks and Adhesives
  - **Inhalation(Vapor):** PDR = 8.9E+0 mg/day over 250 days/yr
  - **Dermal (Liquid 100.00% concentration):** 2.2E+3 mg/day over 250 days/yr (Unloading Liquid Raw Material from Drums)

  USE1: Application of Coatings, Inks and Adhesives
  - **Inhalation(Vapor):** PDR = 1.3E+1 mg/day over 250 days/yr (Unloading Liquid Raw Material from Drums)
  - **Inhalation (mist):** PDR = 2.3E+1 mg/day over 250 days/yr ("What-if") (Basis: Spray Coating)
  - **Inhalation (particulate):** PDR = 2.6E+0 mg/day over 250 days/yr (Basis: Roll coating)
  - **Dermal (Liquid 70% concentration):** 7.7E+3 mg/day over 250 days/yr (Basis: Spray Coating)

  PROC2: Formulation of Cleaning Fluids
  - **Inhalation (Vapor):** PDR = 1.2E+2 mg/day over 250 days/yr
  - **Dermal (Liquid 100.00% concentration):** 2.2E+3 mg/day over 250 days/yr (Unloading Liquid Raw Material from Tank Trucks)

  USE2: Use of Cleaning Fluids

- **Inhalation (Vapor):** PDR = 9.6E-2 mg/day over 250 days/yr
- **Dermal (Liquid 5% concentration):** 1.1E+2 mg/day over 250 days/yr (Unloading Liquid Raw Material from Drums)

PROC3 and USE3: Agrochemicals Formulating and Applying

- **Inhalation (Vapor):** PDR = 1.9E+2 mg/day over 250 days/yr
- **Inhalation (Vapor):** PDR = 5.9E+2 mg/day over 250 days/yr
- **Inhalation (Vapor):** PDR = 1.4E+1 mg/day over 10 days/yr (Loading/Unloading Liquid Product from Drums)
- **Inhalation (Vapor):** PDR = 2.8E+0 mg/day over 10 days/yr ("What-if") (Applying using Tractor with Spray Boom)
- **Dermal (Liquid 100.00% concentration):** 2.2E+3 mg/day over 250 days/yr (Unloading Liquid Raw Material from Tank Trucks)
- **Dermal (Liquid 45% concentration)**: 1.0E+3 mg/day over 250 days/yr (Loading Liquid Product into Drums)

PROC4: Formulation of Metal Working Fluids

- **Inhalation (Vapor):** PDR = 1.8E+0 mg/day over 250 days/yr
- **Dermal (Liquid 100.00% concentration):** 2.2E+3 mg/day over 250 days/yr (Unloading Liquid Raw Material from Tank Trucks)

USE4: Use of Metal Working Fluids

- **Inhalation (Vapor):** PDR = 1.1E-1 mg/day over 247 days/yr
- **Inhalation (Mist):** PDR = 9.6E+0 mg/day over 247 days/yr (Metal Shaping Operations)
- **Dermal (Liquid 35% concentration):** PDR = 2.6E+2 mg/day over 247 days/yr (Unloading Liquid Raw Material from Drums)

PROC/USE5: Chemical Intermediate

- **Inhalation (Vapor):** PDR = 2.0E+2 mg/day over 250 days/yr
- **Dermal (Liquid 100% concentration):** PDR = 2.2E+3 mg/day over 250 days/yr (Unloading Liquid Raw Material from Tank Trucks)

- **General Population Exposure:**
  - Inhalation from fugitive releases with an ADR as high as **4.247E+0 mg/kg/day** and LADD as high as **3.99E-03 mg/kg/day**

- **Consumer Exposure:**
  - Dermal ADR as high as **3.93E+1 mg/kg/day;** LADD as high **as 6.08E-2 mg/kg/day**
  - Inhalation ADR as high as **1.31E+1 mg/kg/day (3.55E+1 mg/m^3)**; LADD as high **as 8.09E-3 mg/kg/day**

RISK CALCULATIONS:

Risks evaluated only for aerosol exposure, as no adverse effects were observed with vapor exposure.

- **Workers:**

Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR															
	Animal or Human POD			Worker Exposure				Human Breathing Rates						Benchmark MOE	Endpoint Type
Exposure Route	POD Conc. mg/m³	POD Period hrs/day	POD Duration days/wk	Exposure mg/day Potential Dose Rate (PDR)	Total Worker Breathing Volume for PDR Exposure Period m³	Worker Exposure Duration Hours/Day	Exposure Duration Days/Wk	Default	Worker	Structural Alert as % of PMN	POD Conc - Duration & Breathing Rate Correction Scenario$_{HEC}$ mg/m³	Exposure TWA mg/m³	**Margin of Exposure MOE**	100	NOAEL
Inhalation	2.2E+02	6.00	5	2.3E+01	10.0	8.00	5	4 90	10.00	100%	8.1E+01	2.3E+00	**3.5E+01**	Fold Factor =	2.8

Although risks were identified for adverse lung effects (increased lung weight based on the accumulation of oil-laden lung macrophage) using a POD based on the NOEC = 220 mg/m^3, this effect is unlikely to occur under the identified conditions of use based on the physical/chemical properties of the PMN substance which are expected to limit aerosol formation (vapor pressure) and increase lung clearance (lower molecular weight, carbon number and viscosity) as compared to C20-C50 hydro-treated oil. For this reason, the NOEC = 1000 mg/m^3 was selected as a POD for risk estimation.

Worker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR															
	Animal or Human POD			Worker Exposure				Human Breathing Rates						Benchmark MOE	Endpoint Type
Exposure Route	POD Conc. mg/m³	POD Period hrs/day	POD Duration days/wk	Exposure mg/day Potential Dose Rate (PDR)	Total Worker Breathing Volume for PDR Exposure Period m³	Worker Exposure Duration Hours/Day	Exposure Duration Days/Wk	Default	Worker	Structural Alert as % of PMN	POD Conc - Duration & Breathing Rate Correction Scenario$_{HEC}$ mg/m³	Exposure TWA mg/m³	**Margin of Exposure MOE**	100	NOAEL
Inhalation	1.0E+03	6.00	5	2.3E+01	10.0	8.00	5	4 90	10.00	100%	3.7E+02	2.3E+00	**1.6E+02**	Fold Factor =	0.6

Risks were not identified for workers via inhalation based on quantitative hazard data for the analogue, C20-C50 hydro-treated oil (MOE = 160; benchmark MOE = 100).

- **General Population and Consumers:**

Consumer and General Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR											
	Animal or Human POD			Population Exposure						Benchmark MOE	Endpoint Type
Inhalation Exposure Scenario	POD Conc. mg/m³	POD Period hrs/day	POD Duration days/wk	Exposure (24-hr conc.) (mg/m3)	Population Exposure Duration Hours/Day	Exposure Duration Days/Wk	Structural Alert as % of PMN	POD Conc - Duration Correction - Scenario$_{HEC}$ mg/m³	**Margin of Exposure MOE**	100	NOAEL
C- Fugitive Air	1.0E+03	6.00	5	3.6E+01	24.00	5	100%	2.5E+02	**7.0E+03**		
GP- Fugitive Air	1.0E+03	6.00	5	4.3E+00	24.00	5	100%	2.5E+02	**5.9E+04**		

Risks were not identified for the general population via inhalation based on quantitative hazard data for the analogue, C20-C50 hydro-treated oil (MOE =7E+3; benchmark MOE = 100).

Population/Consumer Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR											
	Animal or Human POD			Population Exposure						Benchmark MOE	Endpoint Type
Inhalation Exposure Scenario	POD Conc. mg/m^3	POD Period hrs/day	POD Duration days/wk	Exposure (24-hr conc.) (ug/m3)	Population Exposure Duration Hours/Day	Exposure Duration Days/Wk	Structural Alert as % of PMN	POD Conc - Duration Correction - $Scenario_{HEC}$ mg/m^3	**Margin of Exposure MOE**	100	NOAEL
Latex Paint	1.0E+03	6.00	5	3.6E+01	24.00	5	100%	2.5E+02	**7.0E+03**		

Risks were not identified for consumers via inhalation based on quantitative hazard data for the analogue, C20-C50 hydro-treated oil (MOE = 7.0E+3; benchmark MOE = 100).